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(54) EO Biological test pack

(57) The pack for testing the efficacy of ethylene oxide sterilization has a clear plastic tray containing a sterilization sensitive ink which has been imprinted on a card which faces out of the bottom of the plastic tray. The tray contains a plastic syringe which holds a biological indicator and an absorptive material adapted to absorb moisture and ethylene oxide with the syringe. The ratio of the volume of absorptive material in the syringe to the volume of the syringe is comparable to the ratios of prior art test packs which were of much larger construction. A test pack comprising e.g. a syringe containing a biological indicator with an adsorbent member typically of sponge or blotting paper adjacent the syringe opening is also disclosed.

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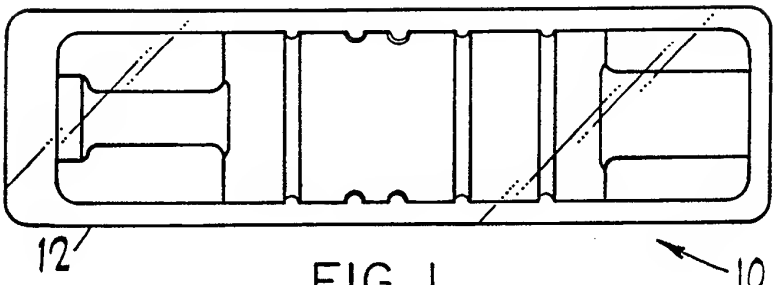

FIG. 1

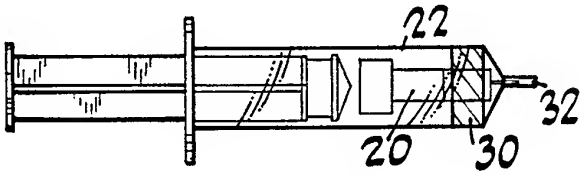

FIG. 2

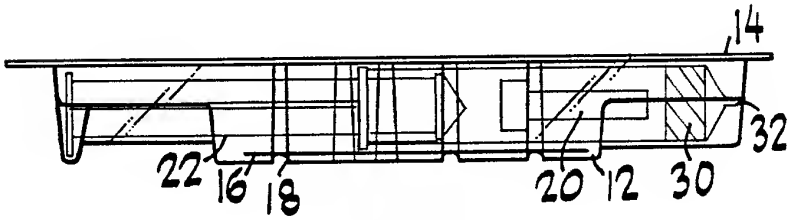

FIG. 3

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EO BIOLOGICAL TEST PACK

The present invention relates to a biological test pack of the type used in hospital sterilization procedures. In particular, the invention relates to a biological test pack of the type used in ethylene oxide (EO) sterilization procedures.

Ethylene oxide gas is commonly used in sterilizing items for use in health care facilities. A common method of testing for the efficacy of the EO sterilization process is to include a biological indicator in the load being sterilized. A biological indicator is a suspension of a large number of bacterial spores that has been dried on a carrier, e.g., paper, and then inserted into a package, such as a glassine envelope or a plastic vial. The spore suspension is typically comprised of a bacterial species that is very resistant to EO. For example, Bacillus subtilis may be used,

and it may be present on the carrier in large numbers. Accordingly, the spore suspension acts as an indicator for the effectiveness of the EO sterilization process. If large numbers of a very EO resistant organism are placed in a load, and if the sterilization process kills those resistant spores, then it is reasonable to conclude that the EO sterilization process was effective.

Since most items that are being EO sterilized are held in some sort of packaging which is intended to maintain the sterility of the contents of the pack until the time of their use, it is prudent to enclose the biological indicator inside similar packaging in order to equalize the challenge of killing the spores on the biological indicator.

In order to standardize the packaging challenge, the Association for the Advancement of Medical Instrumentation (AAMI) has issued an AAMI Recommended Practice entitled "Good Hospital Practice: Performance Evaluation of Ethylene Oxide Sterilizers -- Ethylene Oxide Test Packs". That document recommends the use of a standardized routine test pack for general purpose EO sterilizers in which the biological indicator as well as a chemical indicator can be positioned, and also the use of a more resistant challenge pack for newly installed EO sterilizers. The recommended standard challenge test packs consist of a plastic syringe enclosing a biological indicator, the syringe being wrapped in a properly-sized

cotton towel, and this entire assembly enclosed inside a wrapping or pouch.

The making of an EO test pack is often a tedious process, as the test packs are laborious to construct, and not all of the necessary materials and components may be present at the institution. In addition, there is no standardized method of manufacturing or selecting the components. Compounding this problem is the fact that the surgical (huckaback) towel component of the test pack, which acts as a heat sink and moisture absorber in the test pack, is inherently susceptible to variation, because surgical towels are subject to large changes in their characteristics. For example, after each successive laundering, a surgical towel loses some of its fiber content and thus its capacity to provide a heat and moisture challenge. If it is laundered and then ironed, the towel may be so dry that it provides too much of a challenge to moisture absorption.

In order to minimize the above problems, an improved EO indicator test pack has been developed and is described in U.S. Patent 4,828,797 (Zwarun et al.), assigned to the assignee hereof. The disclosure and drawings of the patent are incorporated by reference herein and discloses a test pack which yields the same rate of survival or death of a biological indicator as does the AAMI-described pack, but which is fully disposable. This test pack is of standardized construction and eliminates variations from pack to pack by being preloaded with an

appropriate biological indicator to eliminate labor required for assembly. The pack behaves in a manner which is equivalent to the biological indicator test pack recommended by AAMI for routine use in general purpose EO sterilizers.

While the aforementioned test pack constitutes a significant advance over the prior art, some improvements have been discovered. For example, the volume of materials used in this test pack required that the pack be fairly large to accommodate the quantity of blotter paper necessary to absorb the humidity and ethylene oxide to a sufficient degree to create a challenge equal to a huckaback towel. It has been found that by decreasing the size of the tray holding the test pack components while substituting an alternative absorptive material for the blotter paper an equivalent amount of absorption of humidity and ethylene oxide could be achieved also while providing a tortuous path. Depending upon the efficiency of the alternative absorptive material, the entire test pack could be made in a range of selected smaller sizes because the relative ratio of the volume of blotter paper to the total volume of the original tray could be made equal to the ratio of the volume of the alternative absorptive material to the volume of the enclosure containing this material.

In the previous test pack, the syringe was situated within a tray which also contained the blotter paper and was covered by a permeable membrane. The relationship between the tray volume and the syringe and the mass and volume of the

blotter paper in the tray created the appropriate challenge that was equivalent to the AAMI described test pack. In this prior art device the volume of the syringe itself was not critical in relation to the volume of the tray. In the present invention, the volume of the tray is still irrelevant so long as there is no impediment to the transfer of ethylene oxide through the tray cover. However, it has been found that an absorptive material, when inserted into the chamber of the standard syringe maintains the same relationship to the relevant volume inside the syringe as did the blotter paper to the relevant volume inside the prior art tray. That is, the absorptive material used in the present invention is about 97% smaller in volume than the previous blotter paper and is placed inside the syringe, the volume of which is about 96% smaller than the volume of the tray. The absorption of humidity achieved by this amount of absorptive material is essentially the same as the absorption achieved by the blotter paper used in the previous version (i.e. about 8-10% by weight of the absorptive material). In effect, the invention enables a much smaller volume to be used to produce the equivalent challenge.

The present invention aims to produce a standard ethylene oxide test pack in smaller sizes than those previously available.

According to the invention, a standard, disposable ethylene oxide biological test pack comprises:

(a) a tray including syringe holding means molded therein for holding a syringe containing a biological indicator;

(b) indicator card holding means associated with said tray for holding an indicator card adjacent to the bottom of said tray in a position in which said indicator card is raised away from possible condensate and is visible from outside of said tray;

(c) a syringe containing a biological indicator of the type including a glassine enclosed or a self-contained biological indicator, said syringe being held in place within said tray by said syringe holding means;

(d) an indicator card having a sterilization sensitive ink imprinted thereon, said indicator card being held in said tray by said indicator card holding means with said ink imprint facing out of said tray; and

(e) an absorbent member situated within said syringe adjacent the opening thereof; and

(f) means for sealing the top of said tray until it is ready for use.

The invention will now be described by way of non-limiting embodiments with reference to the accompanying drawings, in which:-

Figure 1 is a top view of the tray of an example of a test pack according to the present invention;

Figure 2 is a side view of the syringe included in the test pack of Figure 1;

Figure 3 is a side view of the test pack of Figure 1 including the syringe of Figure 2.

Refering generally to Figures 1-3, the test pack 10 of the present invention is constructed of a clear plastic blister tray 12 which is sealed with a peel off lid 14, comprised of a synthetic plastics material e.g. "Tyvek" (Trade Mark) in the preferred embodiment of the invention. Alternatively, a paper lid can be used. The structure of the invention is similar in many respects to the test pack of aforementioned U.S. Patent 4,828,797. This patent is incorporated by reference to disclose various structural features not specifically mentioned herein.

Inside the blister tray 12 is an indicator card 16 that is placed on raised bumbs 18 on the bottom of the blister tray 12 in order to prevent any potential condensate from

damaging the indicator card 16. The indicator card 16 is printed with an EO-sensitive ink so it serves as both an internal indicator of the sterilization process and as a record keeping card on which the results of the biological indicator test can be recorded. The indicator card 16 can then be stored with a record keeping system after it has been exposed.

Above the indicator card 16 and resting in a premolded seat in tray 12 is the plastic syringe 22 that contains the biological indicator 20, which may be an envelope-enclosed spore strip or a self-contained biological indicator of the type known in the art or of the type referred to in aforementioned U.S. Patent No. 4,828,797.

Replacing the absorbent paper of the test pack shown in aforementioned U.S. Patent No. 4,828,797 is absorbent plug 30 which is positioned within syringe 22 adjacent the small opening 32 in the end of the syringe. It will be understood that the ratio of the volume of absorbent plug 30 to the volume of the interior of syringe 22 is comparable to the ratio of the volume of the absorbent paper of the test pack of U.S. Patent No. 4,828,797 to the volume of the interior of the tray of that test pack. The particular type of absorptive material chosen for use in the invention must have characteristics such that it is able to function within the lesser volume of tray 12 to perform a function similar to that of the prior art test pack. Any suitable absorptive

material may be used provided its efficiency per unit weight is, in the new, smaller tray, equivalent to that of the blotter paper used in the previous pack. For example, the amount of blotter paper necessary to achieve the same function if placed within the volume of the syringe would not leave enough room in the syringe for the biological test pack indicator. The particular absorptive material used in the preferred embodiment is a closed cell reticulated (sponge) foam known as Prestofoam #725 available from the Presto Manufacturing Co., 2 Franklin Avenue, Brooklyn, New York.

The new test pack is smaller than previous devices and consequently, more inexpensive, more efficient because it reduces waste (due to the smaller volume of material to be discarded) and requires less storage space (because its volume is significantly smaller than the previous pack).

The AAMI standards require that a biological indicator be placed inside a syringe. However, depending upon the biological indicator different sizes of syringes may be used. In the preferred embodiment shown in the drawings, the type of biological indicator used requires the use of a 20cc (internal volume) syringe.

While a syringe is not absolutely necessary to the invention, it is an acceptable easily recognized structure in the marketplace. It is certainly possible to create a differently shaped structure to replace the standard syringe and yet maintain the AAMI challenge.

It will be understood by those skilled in the art that numerous other modifications and improvements may be made to the preferred embodiment of the invention disclosed herein.

There has been particularly disclosed a standard ethylene oxide test pack which aims to achieve the results of previously known test packs while being constructed in a more simplified manner.

CLAIMS

1. A biological test pack for use in ethylene oxide sterilization processes comprising:

(a) a tray including syringe holding means molded therein for holding a syringe containing a biological indicator;

(b) indicator card holding means associated with said tray for holding an indicator card adjacent to the bottom of said tray in a position in which said indicator card is raised away from possible condensate and is visible from outside of said tray;

(c) a syringe containing a biological indicator of the type including a glassine enclosed or a self-contained biological indicator, said syringe being held in place within said tray by said syringe holding means;

(d) an indicator card having a sterilization sensitive ink imprinted thereon, said indicator card being held in said tray by said indicator card holding means with said ink imprint facing out of said tray; and

(e) an absorbent member situated within said syringe adjacent the opening thereof; and

(f) means for sealing the top of said tray until it is ready for use.

2. The biological test pack of claim 1 wherein said absorbent member comprises an open-celled foam.

3. An article for biologically challenging (determining) the efficacy of ethylene oxide sterilization processes comprising:

(a) a syringe or other container containing a biological indicator of the type including a glassine enclosed or a self-contained biological indicator; and

(b) an absorbent member situated within said syringe or other container adjacent the opening thereof.

4. A test pack according to claim 1 in which the tray is of clear colourless plastics material, and in which the combination (a) - (e) creates a flow rate limiting tortuous opening.

Patents Act 1977
Examiner's report to the Comptroller under section 17 (The Search Report)

Application number: 9126012.5

Relevant Technical fields

(i) UK Cl (Edition K) G1B (BCB)

(ii) Int Cl (Edition 5) C12Q, G01N

Search Examiner: M R WENDT

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASES: WPI AND CLAIMS

Date of Search: 27 JANUARY 1992

Documents considered relevant following a search in respect of claims 1-4

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
A	GB A 2186974 (CASTLE)	3
A	EP A2 0255229 (SURGICOT)	1,3
A	US A 4828797 (WECK) & EP A2 0254428	1,3
A	US A 4528268 (ANDERSON)	3

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

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